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10/667,214	09/19/2003	Wanda Richard	8574-US	7030
74475	7590	03/09/2009		
Gerber Products Company 12 Vreeland Road, 2nd Floor, Box 697 Florham Park, NJ 07932			EXAMINER HELM, CARALYNNE E	
			ART UNIT	PAPER NUMBER
			1615	
			NOTIFICATION DATE	DELIVERY MODE
			03/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

lynn.moody@us.nestle.com
patentdepartment@nestle.com

Office Action Summary

Application No.

10/667,214

Applicant(s)

RICHARD ET AL.

Examiner

CARALYNNE HELM

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 13, 2009 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the claims now recite that the moisturizer comprises an "oily material" (see claims 1, 8, 21, and 23) which is new matter. Although applicant points to a section in the specification where material that could be described as oily (oils and oil containing emulsions – see page 6 lines 13-19) are recited the terminology "oily material" was never used in the specification. Thus it is not apparent which, if any, particular components were considered as "oily material" by

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applicant at the time of the invention or if any such components were contemplated as part of the moisturizer.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 7-8, 15, 21, and 23 recite viscosity ranges of "from about X to about Y", which renders the claim indefinite. The phrase "from about X to about Y" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Further, the extent of variance permitted by "about" is unclear in the context. Therefore it is unclear whether "about X" simply includes a small deviation (e.g. 10%-20%) or if a larger deviation (e.g. 25%-100%) is included as well. Thus the interpretation of the phrase "from about X to about Y" in this context is unclear as no definitive upper and lower bound can be defined. In the context of viscosities this is particularly troublesome since viscosity values change depending on the temperature at which they are measured (see Wright Physics Education 1977 12:323-325). Therefore one of ordinary skill in the art would not be apprised of the true scope of the invention.

The claims not explicitly recited in the explanation above are also rejected due to their dependence from indefinite claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eriksen et al. (previously cited) in view of Chaussee (previously cited), the Random House Unabridged Dictionary, Dahle (previously cited), and DesLauriers et al. (previously cited).

Eriksen et al. teach a shampoo composition, oil composition (pre-treatment), and method for treating cradle cap (seborrhea dermatitis) in infants and small children (see

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abstract; instant claims 1, 8, 21, and 23). Eriksen et al. also teach a kit that include shampoo, oil pre-treatment, comb, sponge, brush and instructions for reducing or eliminating the condition of cradle cap (see column 4 line 66-column 11 line 10 and claim 20; instant claims 8-10, 13, and 23). This kit is taught to include separate containers (cartons/ primary package) of the shampoo and pre-treatment, along with the scale removal devices and instructions (see column 5 lines 1-3; instant claim 16). Since the articles of Eriksen et al. are taught as a kit and a kit is known to be a case and its contents, where the contents is a collection of supplies for a specific purpose, the presence of a single secondary package is implicit in the teachings of Eriksen et al. (see definition for kit in the Random House Unabridged Dictionary; instant claims 1, 8, 21, and 23). Eriksen et al. go on to teach a method for treating cradle cap (mitigating presence the of scales) where 1) the oil pre-treatment is rubbed (massaged) into the scalp, thereby loosening the scales, 2) a comb is used to remove the scales, and 3) the scalp is shampooed (see column 2 line 40-column 3 line 30, column 9 lines 25-40, and column 10 lines 7-10; instant claims 1-2, 5, and 21). In addition, Eriksen et al. also teach that this process can be repeated as needed, indicating that a single performance of the process may leave some scales on the scalp surface. Eriksen et al. does not specifically teach a separate moisturizer being used in the method and claimed kit, the viscosity of the oil pre-treatment, or that the oil-pretreatment is mineral oil.

Chaussee teaches a composition which imparts enhanced emolliency or moisturizing properties and provides extended protection against formation of dry, scaling skin or inhibiting scaling, flaking, drying and other causes of skin irritation (see

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column 2, lines 15-25 and column 3, lines 10-15). The composition viscosity is taught to be preferably from 2000 to 20,000 cps (column 9 lines 25; instant claims 7 and 15). Chaussee is silent as to the particular machinery used to measure the viscosity; however, absent evidence to the contrary, the compositions of Chaussee would still have viscosities within the claimed range if measured with the claimed machinery and it is incumbent upon applicant to demonstrate otherwise. Chaussee goes on to teach humectants, moisturizers, and emollients to be present in the composition, all of which can be classified as "moisturizing ingredients" (see column 3 line 64-column 4 line 9). A particular moisturizer, emollient, and humectant are each taught present at up to 5% by weight (see column 4 lines 12-20; instant claims 1 and 17-24). Chaussee goes on to teach particular additional emollient components in this composition which include cocoa butter and oils (interpreted as "oily material") (see column 5 lines 65 and column 6 lines 5-65; instant claims 6 and 14). The emollients are taught present at up to 30% by weight of the composition (see column 7 lines 12-16; instant claims 1, 8, and 17-24). Thus it would have been obvious to one of ordinary skill in the art to prepare the composition of Chaussee with an "oily material" and moisturizing agents at 10-50%.

Dahle teaches topical compositions that are suitable for treatment of skin disorders and specifically name cradle cap as one such disorder (see paragraph 4 lines 1-2 and 6-7, paragraph 6; instant claims 1 and 8). Within these compositions, Dahle teaches that mineral oil is included as a suitable and preferred ingredient (paragraph 7 lines 1-3; instant claims 3 and 11).

DesLauriers et al. teach that gelled mineral oil used for health and beauty aid compositions gives them desirable properties, more controlled consistency, and serve as an excellent vehicle for delivery to skin (abstract and column 2 lines 10-15, column 3 lines 8-23; instant claims 4 and 12). A broad range of viscosities for the gelled mineral oils are taught that range from 500 cps to 108,920 cps (see table 15). Within this set are particular taught viscosities of 2328 cps and 5034 cps which are interpreted to correspond to "about 3450 to about 3600 cps" (see instant claims 1, 8, 21, and 23). DesLauriers et al. is silent as to the particular machinery used to measure the viscosity; however, absent evidence to the contrary, the gelled mineral oils of DesLauriers et al. would still have viscosities within the claimed range if measured with the claimed machinery and it is incumbent upon applicant to demonstrate otherwise.

Since Eriksen et al. contemplated a situation where the scalp treatment process would need to be repeated (e.g. remaining scalp scales), it would have been obvious to employ an additional remedy that promotes removal of scales from skin and reduces the tendency of the skin to scale. Application of a separate moisturizer after shampooing that performs these functions would therefore have been an obvious addition to the method of Eriksen et al. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add the composition of Chaussee to the composition of Eriksen et al. such that the kit would also include a moisturizer to be applied after the shampooing step. Chaussee provides guidance and motivation of the artisan or ordinary skill in the art to include "oily material" and moisturizing agent in such a preparation. Further, the teachings of Chaussee that allow

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for variations in the viscosity of the moisturizing composition of their invention, particularly between 2,000 cps and 20,000 cps provide ample reason for one of ordinary skill in the art to optimize this parameter as a matter of routine experimentation to provide the desired physical properties in the end product. Thus the claimed viscosity range for the moisturizer would have been obvious. The teachings of Dahle that point to utilizing mineral oil in the treatment of skin disorders would have made it obvious to one of ordinary skill in the art at the time of the invention to employ mineral oil in the oil pre-treatment taught by Eriksen et al. in view of Chaussee, to facilitate the treatment of cradle cap. Finally, the desirability of gelled mineral oil in topical compositions as taught by DesLauriers et al. would have made it obvious to utilize such a form of mineral oil in the pre-treatment at the time of the invention. Therefore claims 1-24 are obvious over Eriksen et al. in view of Chaussee, the Random House Unabridged Dictionary, Dahle and DesLauriers et al.

Response to Arguments

Applicant's arguments filed January 13, 2009 have been fully considered but they are not persuasive.

Applicant argues that because Chaussee teaches a non-oily composition that it does not meet the claim limitation that an oily material be present in the moisturizing composition. The recitation by Chaussee that the composition is non-oily does not mean it cannot contain an oil. As demonstrated by their own teachings in the reference, oils are particularly contemplated as being present in the invention (see column 5 line 66-

column 6 line 9). Further the "oily" property Chaussee seeks to avoid refers to the feel of the film/coating left on the skin after use of the composition, not the composition itself (see column 3 lines 7-12).

Applicant argues that the amount of alcohols recited by the moisturizer of Chaussee is higher than that used in the claimed method. No limitations regarding alcohol in the composition or method are recited by the claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that the teaching by Chaussee that a particular moisturizer provides emolliency is contrary to the teaching of Eriksen that uses its oil component to loosen cradle cap scales. There was no suggestion in the previous Office Action that the composition of Chaussee be used as the oil pre-treatment in Eriksen, so this argument does not address the actual rejection that was made.

Applicant argues that there was no suggestion to use a skin moisturizing composition with a treatment that already removes scaly layers and reduces the tendency of skin to scale. The method taught by Eriksen et al. contemplated a situation when sufficient removal of scales may not be achieved by the application of a pretreatment, mechanical scale removal, and cleansing with a shampoo, so one of ordinary skill in the art would have found it obvious to employ additional steps to facilitate further removal of scalp scales and reduce the tendency of the skin to form further scales. The composition of Chaussee provides a composition whose application performs such a function and thereby cures the deficiencies of Eriksen. Specifically, the

Chaussee reference teaches the compositions are envisioned as being compatible with any number of personal care compositions (see column 2 lines 12-18). Such personal care compositions would certainly include those that impart their own degree of moisturization. The teachings of Chaussee by no means preclude the use of the taught composition following a shampoo or detergent that also contains moisturizing ingredients. Further, the concept/method where the use of a moisturizing cleanser is followed by a moisturizing after treatment (moisturizing shampoo followed by moisturizing conditioner; moisturizing facial cleanser followed by moisturizing lotion) is very well known in the art and thus would have been an obvious implementation of the method of Eriksen et al. in view of Chaussee.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/Tracy Vivlemore/
Primary Examiner, Art Unit 1635